



November 15, 1998

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The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204



Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) We chose these two brassicas for our Phytolyn product because modern science tells us they also have anti-oxidant properties and nutritive value, all of which make Phytolyn a great detoxifier.\*
- (2) Kale and brussels sprouts can help protect against free radicals. These substances stimulate the body and help protect it against free radicals -- the highly unstable oxygen molecules that damage cell matter, including DNA. In particular, laboratory research conducted at the Tufts University Jean Mayer Institute for Human Nutrition discovered that these two vegetables, among all those tested, are the most effective in neutralizing the highly active hydroxyl and peroxy radicals.\*
- (3) Kale and brussels sprouts can help stimulate body's own system for neutralizing harmful substances. These two substances stimulate two of the body's most powerful detoxification mechanisms -- the cytochrome P450 and the Phase II enzyme systems -- the body's biochemical pathways for converting toxins into harmless or easily excretable substances.\*

These statements are made for a dietary supplement containing vacuum dried kale (organically grown), vacuum dried brussels sprouts (organically grown), and calcium stearate. The name of the product is Phytolyn™.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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